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R.E.D. FACTS

Fenitrothion

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0445, fenitrothion.

Use Profile

Fenitrothion is an organophosphate insecticide and acaricide used for commercial greenhouse and outdoor use on ornamentals, including trees, to control a variety of insects and mites. Fenitrothion also is marketed in two new bait products used to control ants and roaches in and around homes, stores, restaurants, warehouses, and other sites. Two mosquito control products used in other countries (not in the U.S.) to prevent malaria are being voluntarily cancelled by the manufacturer. No food or feed uses are registered, however a food additive regulation is established for residues of fenitrothion in or on wheat gluten imported from Australia.

Fenitrothion is applied to ornamentals using ground-based and hand-held equipment. Annual usage on ornamentals is small and appears to be decreasing. Fenitrothion formulations include a wettable powder, emulsifiable concentrate, and bait.

Regulatory History

Fenitrothion was first registered as a pesticide in the U.S. in 1975, for control of the spruce budworm in forests. EPA issued a Data Call-In (DCI) in 1984 requiring additional chronic toxicity data, and a Registration Standard in July 1987 (PB88-191697) which evaluated the studies submitted in response to the DCI. Certain label restrictions were necessary including

a 24-hour interim reentry interval for greenhouse and nursery ornamental uses, and restricted-use classification for the forestry uses. EPA issued a second DCI in June 1991, and required labeling to reflect the high toxicity to birds, honeybees, and aquatic invertebrates. Precautions were imposed to protect endangered species. The registrant requested cancellation of the forestry uses in 1992.

Through implementation of the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides (WPS), the 24-hour interim reentry interval was converted to a 24-hour interim restricted entry interval. Uses within the scope of the WPS include all commercial and research uses of fenitrothion to produce agricultural plants, including use on ornamentals. Fenitrothion ant and roach bait products, registered in January 1995, fall outside the scope of the WPS.

The Agency currently is requiring additional exposure data for fenitrothion before it can make a regulatory decision on the eligibility of low pressure handwand and knapsack/backpack methods of application. Six fenitrothion products are eligible for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, fenitrothion generally has been shown to be of moderate to high acute toxicity. It is moderately toxic by the acute oral and dermal routes and has been placed in Toxicity Category II (the second highest of four categories) for this effect. It is slightly toxic for acute eye effects and is a mild dermal irritant (Toxicity Category III). Fenitrothion is not a skin sensitizer.

Fenitrothion is classified as a Group E carcinogen, indicating that it is non-carcinogenic to humans. It is a cholinesterase inhibitor as indicated in several chronic and subchronic toxicity tests performed on laboratory animals.

Studies indicate that fenitrothion does not cause reproductive effects. Fenitrothion is not considered to be a mammalian mutagen. Metabolism studies indicate that fenitrothion is excreted in the urine and feces within seven days of exposure.

A rat study did not indicate ocular toxicity. A six-month ocular study on dogs, required by the 1991 DCI, is in reserve status until a test protocol is developed.

Dietary Exposure

Although no food uses currently are registered, people may be exposed to residues of fenitrothion through the diet. A food additive regulation for fenitrothion and two of its metabolites has been established (40 CFR 185.2200(a)) for residues in wheat gluten resulting from postharvest application of the insecticide to stored wheat in Australia. An acute risk to the U.S. population from consumption of Australian wheat gluten is unlikely because gluten is mixed with flour before it is eaten.

Since fenitrothion is not registered for use on any domestic crops, its residues are not expected to enter the diet of food animals in the U.S..

EPA developed a U.S. consumption estimate for Australian wheat gluten, and assessed dietary exposure and risk posed by fenitrothion residues in that commodity. For the overall U.S. population, such exposure represents 3% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure level of the most highly exposed subgroup, children aged 1 through 6, represents 8% of the RfD. If the food additive regulation of 30 ppm is used instead of EPA's consumption estimate, these exposure and risk estimates are doubled to 7% of the RfD for the overall U.S. population and 15% of the RfD for children aged 1 through 6. Dietary exposure and risk are minimal.

Occupational and Residential Exposure

Based on current use patterns, fenitrothion handlers (mixers, loaders, and applicators) may be exposed to this pesticide during and after normal use. Exposure to fenitrothion is most likely to occur during and after its application to ornamentals, either outdoors or in greenhouses. The primary route of occupational exposure is dermal. Inhalation exposure may be acute, intermittent, or chronic.

Although most of the exposure data available were questionable, EPA assessed worker exposure and risk to fenitrothion using the toxicological endpoints dermal toxicity resulting from intermediate exposure, and inhalation toxicity resulting from chronic exposure, both of which may result in cholinesterase inhibition. Exposure estimates are based on the assumption that fenitrothion handlers wear certain personal protective equipment. Margins of Exposure (MOEs) are less than 100 (the margin believed sufficiently protective) for applicators using low pressure handwands and for mixer/loader/applicators using low-pressure or knapsack/backpack equipment. Due to a lack of post-application exposure data, EPA was unable to estimate exposure or risk to workers following use of fenitrothion on ornamentals.

Because they are formulated as enclosed baits, the two fenitrothion ant and roach control products approved in early 1995 for residential use result in considerably less human exposure than the ornamental uses, during and after application.

Human Risk Assessment

Based on the available toxicity studies, EPA has determined that fenitrothion presents a potential acute health hazard. It is of moderate to high acute toxicity and is a cholinesterase inhibitor. However, it has been classified as non-carcinogenic to humans ("Group E"). Dietary exposure to fenitrothion residues in wheat gluten is extremely low, and dietary risk appears to be minimal.

Of greater concern is the risk posed to fenitrothion handlers, particularly mixers/loaders/applicators using low pressure handwands or knapsack/backpack equipment to treat ornamentals. The MOEs for these handlers are inadequate. EPA is deferring a regulatory decision for fenitrothion products applied using these methods until chemical-specific worker exposure studies, due within one year, are submitted. Thus, for ornamentals, high pressure handwand treatment is the only application method eligible for reregistration at this time.

EPA is employing a number of risk mitigation measures to protect fenitrothion handlers. For example, the Agency is requiring "baseline" personal protective equipment (PPE); a 48-hour restricted-entry interval (REI) which is more stringent than the (24-hour) interim REI set by the Worker Protection Standard for Agricultural Pesticides (WPS); and upgraded PPE for early entry. The 48-hour REI is increased to 72 hours when any fenitrothion product is used in an outdoor area where the average rainfall is less than 25 inches per year. (See RED Risk Mitigation and Labeling sections for more details.)

Environmental Assessment

Environmental Fate Assessment

Fenitrothion's major routes of dissipation are biotic microbial mediated processes to carbon dioxide and abiotic aquatic photolysis. Fenitrothion appears to be non-mobile when applied to silty clay loam, silty clay, and sandy loam soils. It appears to dissipate fairly rapidly with a half life of 3 to 25 days, and does not appear to be mobile. Fenitrothion is expected to be slightly persistent and relatively non-mobile in the soil environment. Its metabolites also appear to degrade fairly rapidly to carbon dioxide, and are relatively non-mobile. Residues do not leach below 0-12 inches soil depth.

Ecological Effects

Fenitrothion is highly toxic to birds on an acute basis, and causes chronic effects (reduced egg production) in reproduction studies using bobwhite quail. It is moderately toxic to small mammals and both cold and warm water fish on an acute basis. However, it is highly toxic to aquatic invertebrates, and moderately to very highly toxic to estuarine organisms. It also is highly toxic to bees.

Ecological Effects Risk Assessment

High acute risk is expected for birds consuming grass and insects, and high chronic risk to seed-, insect-, and grass-eating birds will occur, following single as well as multiple applications of fenitrothion at 3 lbs. active ingredient (ai)/acre. Risk quotients for mammals and estuarine/ marine organisms are exceeded. High acute risk to freshwater invertebrates is expected from a single application of fenitrothion. Honey bees exposed to this pesticide may be adversely effected.

To reduce these risks, the registrant has proposed numerous label modifications for products used on ornamentals including a lower use rate, a restriction on the maximum number of applications per year, and an increase in the retreatment interval from one week to one month. (See Risk Mitigation, below.)

Endangered species levels of concern (LOCs) are exceeded for acute effects to aquatic invertebrates and in some instances to birds and wild mammals, as well as for chronic effects to birds and aquatic invertebrates. Limitations on the use of fenitrothion may be required in the future to protect threatened and endangered species when the Endangered Species Protection Program goes into effect.

Risk Mitigation

To lessen the acute toxicity risks of fenitrothion, EPA, in conjunction with the registrant, has developed and is requiring the following risk mitigation measures.

- All fenitrothion products labeled for outdoor use must be classified as restricted use pesticides.
- Use of fenitrothion on Christmas tree plantations, on shade trees other than those in nurseries, and basal bark (drench) treatment are being voluntarily deleted from product labels by the registrant. These uses pose the greatest potential for exposure to non-target species.
- For the remaining ornamental uses, the registrant has proposed significant label revisions to reduce ecological risk, including:
  - Reduce application rate to 0.3125 lbs./acre;
  - Reduce maximum number of applications to three per year;
  - Increase minimum interval between applications to one month;
  - Remove broadcast application from the label, limiting use to spot treatment only.
- Due to concerns about the high acute toxicity of fenitrothion, EPA is establishing baseline personal protective equipment (PPE) requirements for handlers of all end-use products, and is establishing early-entry PPE requirements including dermal protection PPE and protective eyewear.
- Due to concerns about the post-application exposure of agricultural workers, EPA is increasing the interim Restricted Entry Interval (REI) from 24 to 48 hours for all uses within the scope of the WPS. This REI is further increased to 72 hours when fenitrothion products are used outdoors in areas where the average rainfall is less than 25 inches per year. The REI will be reassessed upon receipt and review of the chemical specific exposure data required in the RED.

Additional Data Required

EPA is requiring the following additional generic studies for fenitrothion to confirm its regulatory assessments and conclusions:

- Acute oral LD50 for Bobwhite Quail (3-methyl-nitrophenol);
- Terrestrial Field Dissipation;
- Chronic Toxicity to Birds (**reserved**);
- Six Month Ocular Toxicity Study in Dogs (**reserved**).

Before EPA can make a reregistration eligibility decision regarding the low pressure handwand and knapsack/backpack methods of application, the following studies must be submitted:

- Foliar Dissipation;
- Occupational Post-application Dermal Exposure;
- Occupational Post-application Inhalation Exposure;
- Estimation of Dermal Exposure at Outdoor Sites;
- Estimation of Inhalation Exposure at Outdoor Sites;
- Estimation of Dermal Exposure at Indoor Sites;
- Estimation of Inhalation Exposure at Indoor Sites.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All fenitrothion end-use products must comply with EPA's current pesticide product labeling requirements, and with the following. For a comprehensive list of labeling requirements, please see the fenitrothion RED document.

Restricted Use Classification

All fenitrothion products labeled for outdoor use must be classified for restricted use, and the following statement must appear on product labels:

"Restricted Use Pesticide

Due to toxicity to fish and aquatic organisms.

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

Changes in Rates, Uses, and Number of Applications

The following changes must be made to all ornamental end-use products:

- Restricted use classification;
- Delete Christmas tree farm and Southern Pine Bark Beetle uses;
- Delete broadcast application--all ornamental uses are limited to spot treatments;
- Limit use rate to 0.3125 lbs ai/acre and limit the maximum number of applications per year to three;
- Increase the minimum interval between applications to one month;

- Limit use on shade trees to those in nurseries and/or greenhouses;

- Limit application to high pressure handwands, low pressure handwands, and knapsack/backpack sprayers. .

Personal Protective Equipment (PPE) Requirements

The following minimum, baseline PPE requirements pertain to both WPS and nonWPS uses by occupational handlers:

"Applicators must wear:

- Coveralls over long-sleeved shirt and long pants;

- Chemical-resistant gloves;

- Chemical-resistant footwear plus socks;

- Chemical-resistant headgear for overhead exposure;

- Chemical-resistant apron when cleaning equipment, mixing, or loading;

- Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

Entry Restrictions

EPA is requiring the following entry restrictions for all uses within the scope of the WPS:

"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Each 48-hour REI is increased to 72 hours in outdoor areas where the average rainfall is less than 25 inches per year."

The PPE required for early entry following applications of fenitrothion is:

- Coveralls over long-sleeved shirt and long pants;

- Chemical-resistant gloves;

- Chemical-resistant footwear plus socks;

- Chemical-resistant headgear for overhead exposures; and

- Protective eyewear.

User Safety Statements

EPA is requiring the following user safety statement on all end-use products containing fenitrothion:

User Safety Requirements:

"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Environmental Hazard

The following statement is required for end-use products:

"ENVIRONMENTAL HAZARD

This pesticide is toxic to birds and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Regulatory Conclusion

EPA has determined that products containing fenitrothion are eligible for reregistration **except** products labeled for application to ornamentals using low pressure handwand and knapsack/backpack spray equipment (products applied using high pressure handwand equipment are eligible for reregistration). The use of eligible fenitrothion products in accordance with labeling and risk mitigation measures specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA.

EPA does not have enough information at this time to make an eligibility decision for fenitrothion products labeled for use on ornamentals and applied using low pressure handwand and knapsack/backpack spray equipment. The Agency is requiring additional worker exposure studies in order to develop a more complete data base and make a reregistration eligibility decision regarding these uses of fenitrothion.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for fenitrothion during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher

server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the fenitrothion RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the fenitrothion RED, or reregistration of individual products containing fenitrothion, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.